

REMARKS

The Examiner has objected to the two new claims added by the Amendment of December 7, 2006, as having the same claim number and has renumbered the claims as claims 24 and 25 respectively. Applicants thank the Examiner for renumbering the claims.

Claims 18 and 24 stand rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement. In particular, the Examiner has stated that the limitation “a width of the intervertebral plate being at least about 70% of the width of the intervertebral space” is not supported by the specification language “[The intervertebral plate’s] dimensions in the AP direction and LM direction...are not significantly smaller than those of the intervertebral space. It should be at least 70% of the clear distance between the protrusions of the lower vertebral body, preferably at least 80%” (Specification, page 14, line 31 to page 15, line 1). Applicants believe it would be apparent to a person skilled in the art that the specification language “clear distance between the protrusions of the lower vertebral body” refers to the “width” of the intervertebral space. However, applicants have amended claims 18 and 24 to recite the dimension of the intervertebral plate in the lateral-medial direction to be at least about 70% of the clear distance between the protrusions of the lower vertebral body. Since the amended claims are fully supported by page 14, line 35 to page 15, line 1, of the specification, this rejection should be withdrawn.

Claims 1-7, 9-18, 20, 23, 24 and 25 stand rejected as being anticipated by Michelson. In particular, the Examiner states that Michelson teaches an X-ray marker because the tip and shoulder of the distractor’s leading end (154), the bore (155) on the distractor (151) and the bores (714) and (720) on the milling block (700) can all serve as X-ray markers. However, claims 1 and 9 recite an *intervertebral plate comprising* at least one X-ray marker extending in an *anterior-posterior direction* for positioning the intervertebral plate in the intervertebral space. In other words, the X-ray marker is located on or is a part of the intervertebral plate, and the marker is detectable in the anterior-posterior X-ray beam path, allowing the exact positioning of the intervertebral plate in

relation to the median plane of the vertebral bodies when the X-ray is applied from the front to the back or vice versa through the patient's body.

The bores (714) and (720) on the milling block (700) disclosed by Michelson are not located on an intervertebral plate as claimed, but rather located on the milling block (700). In addition to not being located on an intervertebral plate as claimed, the bore (720) on the milling block (700) is not even detectable in the AP X-ray beam path during the insertion of the intervertebral plate since a pin would be inserted to the bore (720) to position the block (700) after the initial insertion of the intervertebral plate.

On the other hand, as mentioned in the Amendment dated December 7, 2006, the tip and shoulder of the distractor's leading end (154) disclosed by Michelson may not serve as a marker "extending in an anterior-posterior direction" as claimed because the bulky distractor holder (158), which is used in a combined configuration with the distractor (151), blocks the X-ray beam when the distractor's leading end (154) is inserted into the patient's intervertebral space. In addition, the bore (155) on the distractor (151) is not even visible in an AP X-ray beam path. Since Michelson does not disclose an X-ray marker on an intervertebral plate that extends in the anterior-posterior direction as specified in claims 1 and 9, this rejection should be withdrawn as to claims 1-7, 9-15, 24 and 25.

In addition, as to claims 16-18, the Examiner says that Figures 67-69 of Michelson disclose a guide device defining two guide axes in the median plane below and above the adjustment rod. Claims 16, 18 and 23 as amended now recite a guide device which defines two guide axes in the median plane below and above the adjustment rod while *being positioned* or *supported by* the adjustment device comprising an intervertebral plate. The embodiment illustrated in Figure 67 uses two prongs (1151a) and (1151b) to position the guiding member (1110), not an intervertebral plate as claimed. The milling guide (1219) of Figure 68 and 69 has an opening (1218) that is shaped for a milling apparatus (200), not an intervertebral plate as claimed. Since Michelson does not disclose a

guide device which defines two guide axes in the median plane below and above the adjustment rod while being positioned or supported by the adjustment device comprising an intervertebral plate as claimed, this rejection should be withdrawn as to claims 16-18 and 23.

Claim 20 has been amended to recite an instrument set comprising a set of rasps, the largest rasp being substantially similar to the prosthesis in shape and the other rasps being progressively smaller than the largest rasp, the largest rasp having a height substantially similar to that of the prosthesis, the rasps having a surface without teeth on a side that corresponds to a leveled part of the prosthesis, and at least one of the rasps having a handle for manual operation. In other words, claim 20 is directed to a set of rasps that can be used in a sequential manner by manual operation to create a space that custom-fits the prosthesis. Support for the amendment can be found in page 17, line 36, to page 18, line 7, and in Figures 15-20.

The only cutting tool described in detail in Michelson is the milling bit (202) of Figures 16-18, which is configured to be coupled to a motorized drill or gas driven turbine, or other driving device (Michelson, column 15, lines 15-21). While Michelson mentions a rasp at column 16, line 19, the rasp is not described in detail. In addition, the summary of invention section states that the invention of Michelson is directed to “the use of a power milling apparatus such that all free hand motions are eliminated,” implying that the rasp is somehow used with a power milling apparatus. Thus, Michelson concerns a very different method of bone removal and does not disclose or suggest a set of rasps that can be used in a sequential manner by manual operation to create a space that custom-fits the prosthesis like the instrument set specified in claim 21. Accordingly, applicants respectfully request the Examiner to withdraw this rejection.

Claim 22 stands rejected as being anticipated by Bryan. Claim 22 now recites “*sliding* a hub of a guide device *onto* an adjustment rod...in such a way that the guide device defines two guide axes in a median plane...” In making the rejection, the Examiner says that Bryan discloses “pushing a hub (316) of a guide device (318) onto an adjustment rod (308); the guide device

defining two guide axes (314) above and below the adjustment rod and parallel thereto.” However, as illustrated in Figure 26 of Bryan, the shaft (308) of the sagittal wedge (300) does not even come in contact with the support frame (316) of the guide device (318). Thus, Bryan does not disclose “sliding a hub of a guide device onto an adjustment rod” as claimed. Accordingly, this rejection should be withdrawn.

Claim 21 stands rejected under 35 USC 103(a) over Michelson in view of Jacobson. Applicants have amended claim 21 to recite an intervertebral plate comprising an X-ray marker extending in the anterior-posterior direction. As explained above, since Michelson’s distractor (151) is used in a combined configuration with the bulky distractor holder (158) when the intervertebral plate is inserted into the patient’s intervertebral space, Michelson does not disclose an X-ray marker on an intervertebral plate which extends in the anterior-posterior direction as claimed. Jacobson does not disclose any feature that even slightly resembles an intervertebral plate. Accordingly, none of the cited references discloses an X-ray maker located on an intervertebral plate that extends in the anterior-posterior direction as specified in claim 21, and this rejection should be withdrawn.

In view of the above, the pending claims are in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims and pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

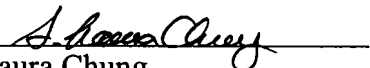
If the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. **246472003920**.

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Respectfully submitted,

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